UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,398	07/27/2006	Myoung Woo Lee	Q96125	3357

23373 7590 06/26/2009
SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
BARNHART, LORA ELIZABETH	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
06/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,398	LEE ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-34* is/are pending in the application.

4a) Of the above claim(s) *7,8 and 12-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,9-11,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/18/09, 7/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 4/6/09 to claim 5 have been entered. Claim 6 has been cancelled. No claims have been added. Claims 1-5 and 7-34 remain pending in the current application.

Election/Restrictions

Applicant's election with traverse of Group II, claims 5, 33, and 34 (claim 6 has been canceled and its limitations incorporated into claim 5), in the reply filed on 4/6/09 is acknowledged. The traversal is on the ground(s) that the product of claim 5 makes a contribution over the prior art and is, therefore, a special technical feature. After a search of the prior art, the examiner agrees that the cells as claimed are not anticipated or rendered obvious by the art. In accordance with 37 C.F.R. 1.475, applicants are entitled to examination of the first recited method of making this product (claims 1-4) and the first method of using this product (claims 9-11).

Applicant's election of the species "Parkinson's disease" relating to claim 34 in the same reply is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The remainder of the restriction requirement is still deemed proper and is therefore made FINAL. Claims 7, 8, and 12-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no

allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/6/09.

Examination on the merits will commence at this time on claims 1-5, 9-11, 33, and 34 ONLY, to the extent they read on the elected species where applicable.

Claim Objections

Claims 1-3, 5, and 9-11 are objected to because of the following informalities.

Claims 1 and 5 omit spaces in elements 1 and 3: "fetal bovine serum_(FBS)."

Claims 2, 3, and 9 recite the unit "Ml," but the examiner suspects applicant intends to recite milliliters (mL), not megaliters (ML).

The word "and" appears to have been omitted from line 2 of claim 3 ("...glutamine, and 10...")

The word "isolated" is misspelled at line 3 of claim 5. Finally, claim 5's preamble does not comply with standard English usage ("a cell ... the cell being isolated and cultured" would be more correct). Appropriate correction is required.

The word "forskolin" is misspelled at line 3 of claim 9 and line 2 of claim 10.

Claim 11 should read "and cultured" at line 3, not "and culturing."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 9-11, 33, and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 5 is drawn to a cell that can be made by particular culturing steps (1-3) and is characterized as showing "positive" reactions against a few antibodies, "negative" reactions against another set of antibodies, "positive and partial positive" reactions against a third set, "negative and partial negative" reactions against a fourth set, and "negative and partial positive" reactions against a fifth set of antibodies. Claim 33 is drawn to a composition comprising the cells of claim 5. Claim 34 sets forth some intended uses of the composition of claim 33. The examiner notes that claim 34 has not been addressed on its merits beyond the elected species and compliance with 35 U.S.C. § 112, second paragraph.

The as-filed specification does not indicate that a cell having the properties of the claimed cell was possessed by applicant at the time of the invention. See M.P.E.P. § 2163. Page 20, lines 15-21, of the specification include a working example describing the multipotent progenitor/stem cells yielded by steps encompassed by the steps in the claims:

The multipotent progenitor/stem cells isolated and cultured from the cord blood-derived mononuclear cells according to the method of the present invention indeed showed the immunophenotype profile having positive reactions against antibodies for CD 14, CD31, CD44, CD45 and CD54 antigens; negative reactions against antibodies

for CD34, CD49a, CD62E, CD73, CD90 and CD133 antigens; and partial positive reactions against antibodies for CD104, CD105 and CD166 antigens.

The results of Example 2 (page 20) do not appear to correlate with the claimed properties of the cells. For example, the specification indicates that the cells react with CD54, but the claims allow that the reaction may be "positive and partial positive." The specification demonstrates that the cells do not react with CD49a, but the claims allow that the reaction may be "partial positive"; the opposite is true for CD104, which is characterized in the specification as "partial positive" but claimed as "negative and partial positive." CD105 is characterized as "partial positive" but claimed as "negative and partial positive." The experimental data do not clearly support the cell population as claimed. The examiner notes that the broad disclosure at page 11, lines 8-20, appears to correlate with the markers as recited in the claims, but the disconnect between the broad disclosure and the working examples is queried.

The method of claim 1 and its dependents appears to correlate to the method of Example 1 (specification, page 17 et seq.), which is taught in the specification as giving rise to the cells of Example 2 (i.e., those that do not appear to correlate to the claimed cells). Therefore, the examiner finds that the steps recited in claim 1 do not give rise to the cell product recited in claim 1. Similarly, because claims 9-11 require the cell of claim 5 as a starting material, applicant cannot have possessed that method of use without possessing the starting cells. Claims 1-4, 9-11, 33, and 34 do not rectify the issue of possession and must therefore also be rejected under 35 U.S.C. § 112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 9-11, 33, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 refer to "a cord blood-derived mononuclear cell," which is confusing because it is not clear how closely related a cell must be to cord blood cells to be considered "derived" from cord blood. Clarification is required. If applicant intends to require that the cell be isolated from cord blood, the claims should so indicate.

Step (1) in the method recited in claims 1 and 5 refers to "supplementary elements," but it is not clear what is being supplemented. It is not clear which components are encompassed by this claim term and which are not. Clarification is required. Claims 9 and 10 include the same limitation and are therefore indefinite for the same reason.

Claim 5 is drawn to a cell that can be made by particular culturing steps (1-3) and is characterized as showing "positive" reactions against a few antibodies and "negative" reactions against another set of antibodies; claim 1 is drawn to the method for making this cell. However, the claims also require that the cell show "positive and partial positive," "negative and partial negative," and (most confusingly) "negative and partial positive" reactions against other subsets of antibodies. The degree of "negative" and "positive" included in and excluded by the limitations "partial negative" and "partial positive" is not clear. This language does not particularly point out the properties the cell

necessarily possesses and which it may not. As discussed in the written description rejection above, the claim language is particularly confusing in light of the teachings of the specification at page 20, lines 15-21. Clarification is required.

Because claims 2-4, 9-11, 33, and 34 depend variously from indefinite claims 1 and 5 and do not clarify these points of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 11 requires that the cells be seeded at a "concentration" of a certain number per "cm^2," which is confusing. Concentration should be expressed as units per volume, not area. Clarification is required.

Claim 34 provides for the use of the cell composition of claim 33, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Clarification is required.

Furthermore, it is not clear which conditions are treated by the composition of claim 34, since the claim includes all of the conditions in an "and" phrase (as opposed to a Markush group, e.g.). Clarification is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 34 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper

definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). In addressing this rejection, applicant should note that in accordance with 37 C.F.R. 1.475, examination will be carried out on the first recited method of using the composition of Group II (i.e., claims 9-11) only.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 33, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Luderer et al. (1980, U.S. Patent 4,190,535; reference A) taken in light of Reid et al. (2005, U.S. Patent Application Publication 2005/0148072; reference B) and Atala (2003, U.S. Patent Application Publication 2003/0211602; reference C). In the interest of compact prosecution, the claims are interpreted as being drawn to a cell that shows positive reactions against antibodies for CD14, CD31, CD44, and CD45 and negative reactions against antibodies for CD34, CD62E, CD90, and CD133; as discussed in the indefiniteness rejection, the limitations regarding "partial positive" and "partial negative" do not clearly limit the scope of the product in any meaningful way.

Luderer teaches isolated monocytes (column 2, lines 23-34; and column 5, line 44, through column 6, line 52).

Reid is cited solely as evidence that CD14 and CD31 are markers of monocytes and CD44 and CD45 are markers of leukocytes (of which monocytes are a subset). Reid further teaches that CD54 is a marker of endothelial cells and CD62 is a marker of platelets (paragraph 320).

Atala is cited solely as evidence that CD90 is a marker of mesenchymal stem cells, and CD133 is a marker of hematopoietic stem cells (paragraph 32)

The monocytes of Luderer, because they are monocytes, by definition express monocyte markers (CD14, CD31, CD44, and CD45) and do not express markers of disparate cell types (e.g, endothelial cells, platelets, MSCs, and HSCs; CD54, CD62, CD90, and CD133, respectively).

This rejection would be overcome by amending the claims such that they particularly require the cell to express a combination of markers that are not expressed exclusively by monocytes.

No claims are allowed.

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, **not** the published application. Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims and share an inventor or assignee with the instant application. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651